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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,256

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Hanns-Georg Klein

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,256	Applicant(s) KLEIN, HANNS-GEORG	
	Examiner TERESA E. STRZELECKA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to an after-final amendment filed March 3, 2009. Claims 9-16 were previously pending. Applicant amended claims 9 and 12. Claims 9-16 are pending and will be examined.

2. Applicant's amendments overcame all of the previously presented claim rejections. Applicant's amendment to the specification obviated the objection presented in the previous office action.

3. Examination of the disclosure regarding the sequence of the NOD2/CARD15 gene and the positions of the polymorphisms claimed revealed discrepancies between Applicant's disclosure and published data, which need to be addressed before the claims can be allowed. Therefore this action presents new grounds for rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9-16 are drawn to a method of predicting the likelihood of an incidence of a disease associated with at least one of the polymorphisms 8, 12, 13 in the NOD2/CARD15 gene by detection of one of the polymorphisms wherein the disease is graft versus host disease.

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Applicant provided the following information regarding the NOD2/CARD15 gene on page 2, lines 12-33 and page 3, lines 1-18):

a) The NOD2/CARD15 gene has accession No. AC007728 and AQ534686 (page 2, lines 12-15).

b) The NOD2/CARD15 gene has 3123 nucleotides and accession No. NM_022162 (page 2, lines 16-18).

c) SNP 8 has accession No. ss2978536 in the NCBI data database and results from the C -> T exchange of the nucleotide position 2209 of the NM_022162 sequence (page 2, lines 30-33).

d) SNP 12 has accession No. ss2978537 in the NCBI data database and results from the G -> C exchange of the nucleotide position 2827 of the NM_022162 sequence (page 3, lines 5-7).

e) SNP 13 has accession No. ss2978539 in the NCBI data database and results from insertion of a C at the nucleotide position 3124 of the NM_022162 sequence (page 2, lines 30-33).

Applicants also provided primers and probes for detection of these polymorphisms on page 15, lines 11-27), SEQ ID NO: 1-12.

However, examination of the sequence databases revealed the following:

A) Nucleic acid sequence with accession No. AC07728 is a sequence of complete chromosome 16, therefore it contains more genes than just the NOD2 gene. Further, this sequence had four different versions since its submission, therefore it is not clear which one of these versions Applicant refers to.

B) Nucleic acid sequence with accession No. AQ534686 has 542 bp, which is shorter than the full NOD2 gene.

C) Sequence with accession No. NM-022162 is uniquely identified, but positions of SNP8, 12 and 13 referred to by Applicant in the specification with respect to the above sequence are

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different from the positions of these SNPs identified in the NCBI SNP database. Specifically, SNP 8 is identified by the SNP database as occurring at a position 2104 of the NM-022162 sequence, SNP 12 is identified by the SNP database as occurring at a position 2722 of the NM-022162 sequence, and SNP 13 is identified by the SNP database as occurring at a position 3016 of the NM-022162 sequence (see enclosed data from the database).

D) Alignment of the primers presented by Applicant for the amplification of fragments containing the polymorphisms with the NM-022162 sequence reveal that these primers flank positions identified by Applicant, not by the database.

Therefore, Applicant has not provided a sufficient written description for the claimed subject matter. Finally, since the sequences and SNPs claimed are essential subject matter, they need to be incorporated by reference into the disclosure.

6. Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Nucleic acid sequences critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Applicant did not provide a SEQ ID NOs for the sequence of the NOD2/CARD15 gene. Applicant provided the following information regarding the NOD2/CARD15 gene on page 2, lines 12-33 and page 3, lines 1-18):

a) The NOD2/CARD15 gene has accession No. AC007728 and AQ534686 (page 2, lines 12-15).

b) The NOD2/CARD15 gene has 3123 nucleotides and accession No. NM_022162 (page 2, lines 16-18).

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c) SNP 8 has accession No. ss2978536 in the NCBI data database and results from the C -> T exchange of the nucleotide position 2209 of the NM_022162 sequence (page 2, lines 30-33).

d) SNP 12 has accession No. ss2978537 in the NCBI data database and results from the G -> C exchange of the nucleotide position 2827 of the NM_022162 sequence (page 3, lines 5-7).

e) SNP 13 has accession No. ss2978539 in the NCBI data database and results from insertion of a C at the nucleotide position 3124 of the NM_022162 sequence (page 2, lines 30-33).

Applicants also provided primers and probes for detection of these polymorphisms on page 15, lines 11-27), SEQ ID NO: 1-12.

However, examination of the sequence databases revealed the following:

A) Nucleic acid sequence with accession No. AC07728 is a sequence of complete chromosome 16, therefore it contains more genes than just the NOD2 gene. Further, this sequence had four different versions since its submission, therefore it is not clear which one of these versions Applicant refers to.

B) Nucleic acid sequence with accession No. AQ534686 has 542 bp, which is shorter than the full NOD2 gene.

C) Sequence with accession No. NM_022162 is uniquely identified, but positions of SNP8, 12 and 13 referred to by Applicant in the specification with respect to the above sequence are different from the positions of these SNPs identified in the NCBI SNP database. Specifically, SNP 8 is identified by the SNP database as occurring at a position 2104 of the NM_022162 sequence, SNP 12 is identified by the SNP database as occurring at a position 2722 of the NM_022162 sequence, and SNP 13 is identified by the SNP database as occurring at a position 3016 of the NM_022162 sequence (see enclosed data from the database).

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D) Alignment of the primers presented by Applicant for the amplification of fragments containing the polymorphisms with the NM-022162 sequence reveal that these primers flank positions identified by Applicant, not by the database.

Therefore, Applicant has not provided a sufficient written description for the claimed subject matter. Finally, since the sequences and SNPs claimed are essential subject matter, they need to be incorporated by reference into the disclosure.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are indefinite and vague because the claims are written in the passive tense. Method claims should recite positive, active process steps (see Ex parte Erlich 3 USPQ 2d 1011). This rejection may be overcome by amending the claims to recite the active tense, e.g. "denaturing the DNA...". For example, claim 9 does not contain a single active step, and claims 10-12 contain a mixture of active and passive method steps.

Incorporation by Reference

9. The attempt to incorporate subject matter into this application by reference to GenBank accession numbers and NCBI SNP database is ineffective because no statements about incorporating this subject matter were presented in the disclosure, and the root words "incorporate" and/or "reference" have been omitted, See 37 CFR 1.57(b)(1) and the reference document is not clearly identified as required by 37 CFR 1.57(b)(2)).

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10. The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

11. No references were found teaching or suggesting claims 9-16, but they are rejected for reasons given above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
March 13, 2009